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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,146	11/17/2000	Christopher T. Boyle	6006-018	6734

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EXAMINER	
MILLER, CHERYL L	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 10/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/716,146	BOYLE, CHRISTOPHER T.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,20 and 26-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,20 and 26-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 16, 20, and 26-28 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to the rejection of claims 16, 20, and 26-28 over the Brown et al. reference (US 6,071,305) have been considered however are found non-persuasive. Applicant has again argued that Brown does not anticipate structural elements having separate layers, specifically, that Brown does not disclose a void space between two layers. The examiner disagrees. Brown has disclosed many embodiments having the layers as claimed. One embodiment is shown in figure 5 (see attachment 1), wherein one layer (seen in yellow) may be considered element 12'' and another layer (seen in red) may be considered 34 (it is noted to the applicant, that although the structural elements are claimed to be fabricated of metal, the "layers" are not required by the claim to be metal; that is the structural elements as a whole need only *comprise* metal and may include other materials as well), the void layer 20 being therebetween. Another embodiment is shown in figure 7 (see attachment 2), wherein one layer (seen in yellow) may be considered the outer perimeter of element 40, and an additional layer may be considered to be 44 (seen in green) or even 49 (seen in red), the void layer 20 therebetween. Also in figure 7 (see attachment 3), one layer (seen in yellow) may be considered the right side of outer perimeter, and a second layer (seen in green) may be on the left side of the outer perimeter (openings may exist in the layers, because the member is disclosed to be optionally made of porous metals), the void space 20 therebetween. Another embodiment in figure 8, (see attachment 3), shows a layer to be the outer perimeter (shown in yellow) and a second layer

(shown in green) and void 20 therebetween. Figure 10 and 12 also show similar separate discrete layers (as applicant has argued are not present and is discussed below). The term "layer" is defined broadly by "a single thickness overlying a surface", and it is noted to the applicant a single thickness is not necessarily a constant thickness. Even so, Brown has shown such thicknesses in all of Brown's figures, and a square cavity in a square cross-sectional element (as disclosed by Brown) provides a single and even constant thicknesses anyhow. The applicant has also argued that Brown does not disclose layers that are separate and discrete (first of all, the applicant has not claimed *discrete* layers), but instead are unitary. The examiners position is that the applicant themselves does not have separate *discrete* layers. The applicant deposits layer upon layer during the fabrication process, in order to make a unitary end product. The unitary end product having the same structure as Brown. The applicant even discloses the use of other fabrication processes besides deposition to arrive at the final end product, some of which do NOT require the use of layers. Brown may not use a deposition process to form the final structure, and may not deposit layer upon layer of material, Brown does however have an end product the same as the applicants. Whether Brown uses laser treatment or deposition to arrive at the final device, the same final product device results. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227, USPQ 964, 966 (Fed. Cir. 1985), see MPEP 2113. That is, in the scope that the applicant has described, "layer" in their specification,

Brown in this case, also has such layers, Brown's elements may be described at a unitary structure made up of many layers. One could call any particular thickness within Brown's element to be a "layer", see attachment 4 and attachment 5.

The applicant has additionally argued that their invention is not only discretely layered, but also unitary as well. It is unclear how the applicant may have both discrete layers and a single unitary structure at the same time. Nonetheless, Brown's stent structure is believe to be disclosed and shown to be the same structure as the applicant's stent, therefore, if the applicant believes their own device to be layered and unitary at the same time, the same can be said for the Brown stent.

The applicant has also argued that some of the embodiments of Brown comprise a polymer, and are not metal. The examiner disagrees. The applicant has claimed that the structural elements are fabricated from metal. That is, they may be fabricated by metal and a polymer, since they are not limited to *only* metal. Brown's elements comprise metal and are believed to read on the claims. It is noted to the applicant, that the structural elements are claimed to comprise metal, however the first *and* second layers are not disclosed to be made solely of metal. Even if both layers were required to be made of metal, Brown has shown several embodiments wherein the interpreted "layers" are both metal (see attachment 2-5).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16, 20, and 26-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown et al. (US 6,071,305, cited in previous office action). The examiner's interpretation of the "layers" in the Brown reference is also pointed out in Attachments 1-5. Referring to claim 16, Brown discloses an endoluminal stent (11, 40'', 111) comprising a plurality of structural elements (element 12 seen in figure 1, however having the structure, mesh or roving wire stents, each elongated member 12 being a filament or fiber which forms a mesh stent, disclosed in col.7, lines 34-40, that is, although Brown has shown a helical stent made of one structural element in fig.1, Brown also discloses use of a stent with multiple structural elements, wires/fibers/filaments, col.7, lines 34-40; or element seen in cross section fig.12 and disclosed in col.11, lines 50-61; or elements 112 in fig.18) forming a radially expandable cylindrical member, the structural elements are fabricated from metal (col.7, lines 12-19) having a wall thickness (thickness of wire/fiber/filaments, shown in fig.3-12 as the cross-sectional dimension), wherein the structural elements (member 12, or member shown in fig.12) are comprised of a base layer and a second layer covering the base layer, further comprising a void space (20) intermediate the base and second layers and enclosed therebetween (see arguments above and attachments 1-5) and a plurality of pores (pores may be openings 22, 28, 54; col.6, lines 12-21 or alternatively pores may be pores in the porous stent material col.10, lines 36-38) passing through at least one of the base and second layers and communicating with the void space (20 or channel) and at least one bioactive agent (23) retained within the void space (20 or channel) and elutable through the plurality of pores (22, 28, 54).

Referring to claim 20, Brown discloses a degradable plug (biodegradable matrix 27 extending into pore, as is seen in figs.3, 7, 9, and 12, see col.8 line 61-67 and col.9, lines 1-7; or membrane 34, 50, see col.9, lines 12-21, which is disclosed to made of the same materials are the biodegradable matrix, col.9, lines 1-5, 17-21) residing within the plurality of pores.

Referring to claim 26, Brown discloses a stent (10, 40'') having structural elements (member 12 in fig.1-10 or member shown in fig.12) comprising a material selected from the group claimed (col.7, lines 12-19).

Referring to claim 27, Brown discloses a bioactive or active agent (23) selected from the group claimed (col.5, lines 1-27).

Referring to claim 28, Brown discloses a void space (20 or channel in fig.12) comprising a plurality of independent internal cavities along the length of the structural elements (a plurality of cavities are shown in fig.9, 10, and 18; and cavities are shown to be intermittent in fig.18).

Claims 16, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Monaco (WO 94/18906, cited previously). See figures 8-10 and respective portions of the specification. Monaco discloses a plurality of structural elements (each layer may be considered a different structural element) forming a radially expandable (Monaco discloses use of titanium or stainless steel, two metals disclosed by applicant to be expandable) cylinder having a wall thickness, the elements fabricated of metal (pg.8, lines 10-12) and comprising a base layer (housing 105) and a second layer (housing 110), further a void space (130) inbetween the two and a plurality of pores (160) passing through one of the layers (both 105 and 110) and a

bioactive agent (cells secreting agent or 135; pg.7, lines 30-32; pg.21, lines 22-25) retained in the void space for release through the pores.

Claims 16, 20, and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Yan (US 5,843,172, cited previously). See figures 6, 11, 12, and respective portions of the specification. Yan discloses an endoluminal stent (104; fig.1, 9) having a wall thickness and metallic structural members comprising a base layer (middle region layer in fig.12; or layer 44 in fig.6) and second layer (outer surface region layers in fig.12; or layer 41 in fig.6), and a void space (larger pores located near the center 52) intermediate the layers and a plurality of openings (smaller pores near surface 54) connecting the cavities to the stents exterior (col.7, lines 1-16; col.8, lines 45-58), and bioactive agents (therapeutic agent) disposed within the cavities.

Yan discloses the tubular member or structural body comprising a material selected from the group claimed (col.4, lines 32-39). Yan discloses a bioactive or active agent selected from the group claimed (col.5, lines 1-30). Yan discloses a degradable plug (coating or matrix 100; fig.11, 12; col.9, lines 15-40) residing within the at least one of the openings.

Claims 16, 26, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Buirge (US 5,735,897). Buirge discloses an endoluminal stent (10; fig.1) having a wall thickness and metallic (discloses polymeric or other materials, col.2, lines 65-67; such as metals, col.5, lines 38-46) structural elements (structural elements may be considered to be the separate layers, or the separate fibers within one layer) comprising a base layer (12) and second layer (16), and a void space (14) intermediate the layers and a plurality of openings (layer 12 is porous; col.2,

lines 53-65) connecting the cavities to the stents exterior, and bioactive agents (therapeutics/drug; col.4, lines 8-27) disposed within the cavities.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER